(2)

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CONTRACTING ORGANIZATION: New Jersey Medical School
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This annual report covers progress from the first year of a five year project evaluating the natural history of HIV infection in pregnancy. This study will establish a cohort of 240 women who are classified as follows: 1) HIV infected pregnant women who are active substance users, 2) HIV infected pregnant women who are not active substance users, 3) HIV negative pregnant women who are substance users and 3) HIV negative pregnant women who are not substance users. During the first year of funding, the work scope was revised in consultation with USAMRDC and NIAID projects officer and revised for final approval by the IRB's of the Army Surgeon General and New Jersey Medical School. Working groups of our study team were established to evaluate patient recruitment, counselling, testing, forms development, data management, biostatistics, laboratory procedures and standardization. The project was activated for full enrollment and collection of data for all parameters by the end of the first project period.

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FOREWORD

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____In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

_✓_For the protection of human subjects, the investigator(s) have adhered to policies of applicable Federal Law 45CFR46.

PI Signature Date

INTRODUCTION

Infection with Human Immunodeficiency Virus 1 (HIV) is manifest as a clinical spectrum ranging from asymptomatic infection to serious immunocompromise associated with opportunistic infections and malignancies (AIDS). As of January 1990, 117,000 cases of AIDS have been reported to the Centers for Disease Control and it is now estimated that between 945,000 and 1.4 million persons in the United States are infected with HIV. Although men make up most of the reported AIDS cases, the number of cases among women is steadily increasing.

Women now account for approximately 10% of all AIDS patients in the US and in some states, such as New Jersey, this figure is as high as 16%. Fifty two percent of female AIDS patients acquired the virus as a result of intravenous drug use and 29% by heterosexual contact. The latter represents one of the most rapidly growing risk factors for HIV among women. When persons who have acquired HIV by homosexual or bisexual contact are removed from the national statistics, the male-to-female ratio is 2.9:1. Eighty percent of all women with HIV infection are of childbearing age. The rates of HIV infection among sexually active and pregnant women vary by geographic region. In New Jersey and New York seroprevalence rates for HIV in pregnant women are as high as 5%. In Newark, New Jersey one of 23 infants delivered at the University Hospital are born to mothers that are infected with HIV.

The natural history of HIV infection in pregnancy is incompletely understood. Early studies suggested that pregnancy may adversely affect the course of HIV infection because it is known that this is a time of natural immunologic alteration. Investigations in Miami and New York demonstrated that many asymptomatic HIV-infected women develop HIV symptoms between 28-60 months of delivery. In contrast, prospective studies of asymptomatic pregnant women have reported that acceleration of HIV disease progression during pregnancy is uncommon.

Perinatal transmission represents the primary route of HIV infection for children. Over 80% of all pediatric patients have been infected by this route. Available data suggests that the rate of transmission from an infected mother to her infant if between 25-40%.

These infants may acquire HIV either in utero or at the time of delivery by contact with infected blood and secretions. Once infected, HIV infection in children has a bad prognosis. The incubation period for perinatally acquired infection is shorter than for infection acquired as an adult. Clinical symptoms usually appear early and invariably progress. Fifty percent of children with AIDS are diagnosed in the first year of life and 82% by 3 years of age. Crude mortality statistics from the CDC indicate that over 60% of children with AIDS have died; the median survival after diagnosis is 9 months.

Despite significant advances, there are still significant gaps in our understanding of perinatal HIV transmission. Some of the important areas for research include 1) the mechanism and timing of perinatal HIV infection and 2) factors that influence the transmission (or lack of transmission) from mother to child. It is clear that the mother/infant pair represents an important model of HIV infection and may hold many of the clues to our understanding of HIV pathogenesis. It is through study of this population that we will gain knowledge about the factors that foster transmission of HIV and, perhaps more importantly, those that "protect" some infants from infection despite exposure to the virus.

The project funded under this contract is designed to study the mother/infant model of HIV infection in an attempt to discover factors that influence perinatal transmission of HIV. This will be accomplished through a study of the natural history of HIV infection in pregnancy, including the monitoring of clinical, immunologic, and retrovirologic parameters and correlating this data with the HIV infection status of the infant.

BODY

METHODS:

In order to accomplish the primary objective of this project, namely to study the natural history of HIV infection in pregnancy, the following groups of pregnant women are included (anticipated enrollment goals are given in parentheses):

Group 1: HIV-infected pregnant women who are active substance users (n=80)

Group 2: HIV-infected pregnant women who are NOT active substances users (n=40)

Group 3: HIV negative pregnant women who are substance users (n=48)

Group 4: HIV negative pregnant women who are NOT substances users (n=72)

Groups 3 and 4 are included as controls which are necessary to assess the relative influence of substance use versus HIV on pregnancy course, neonatal outcome and changes in clinical and laboratory parameters.

Pregnant women who are seen for prenatal care at the University Hospital obstetrical clinic and who are 18 years of age or older are counselled and evaluated for HIV infection using ELISA and Western Blot. Eligible patients who consent to participation are enrolled and monitored prospectively according to the schedule outline on the mother's flow sheet APPENDIX A. Mothers will be followed throughout the course of their pregnancy, at labor and delivery and then postnatally up to 6 months. Infants born to mothers in Groups 1 & 2 will be eligible for enrollment into an ongoing study of the natural history of HIV infection in infants born to seropositive mothers that is funded by the Centers for Disease Control. Data regarding the ultimate HIV infection status of these infants will be available.

Any infant who is not enrolled into the CDC study from Groups 1 & 2 as well as all babies born to mothers in groups 3 & 4 will be monitored to determine their HIV infection status as shown in the babie's flow sheet in APPENDIX A.

PROGRESS:

This project is funded through a collaboration between the Epidemiology Branch of the National Institute of Allergy and Infectious Diseases and The US Army Medical Research and Development Command. The contract for this project was awarded September 30,1988. At that time, the Institutional Review Board of the UMD-New Jersey Medical School approved the original study design and plans were in progress to start-up the project. Personnel recruitment was instituted and working groups were established in the following areas:

1. Patient recruitment, retention, counselling and testing
2. Forms development, data management, biostatistics
3. Laboratory procedures and laboratory standardization

Immediately upon contract award we were informed that the NIAID was implementing a multicenter study of HIV in women and their infants and discussion should ensue regarding the pros and cons of our project becoming integrated into this multicenter study. A request was made that we not proceed further until this issue was resolved.

In December 1988, a decision was made and endorsed by us that the Newark project remain independent. It was felt by all parties concerned that we should retain the advantage of a single site study. As we proceded an important early issue for the study was laboratory quality assurance. NIAID, Army representatives and the local study team felt strongly that all retrovirologic, immunologic and serologic testing should meet the standards of the NIAID quality assurrance program. During late 1988 and early 1989 virology (virus isolation), flow cytometry, p24 antigen detection and HIV serology were standardized and we successfully enrolled in the NIAID program.

Over this project period, all budgeted laboratory equipment items were reviewed by the USAMRDC contract officer and upon approval purchase initiated by our study team. New laboratory personnel were identified for the positions supported by this program, hiring process completed and and each individual trained to perform the immunologic and virologic laboratory parameters which are included in the protocol. Internal and external quality controls programs were established and proficiency validated for all laboratory studies prior to the start of patient enrollment. Computerization of laboratory data including the development of an electronic tracking of repository specimens was also accomplished during this period.

It should be noted that around the time of grant award and start-up there were several significant personnel changes within the agencies involved in this grant. All of the original discussions regarding the design and implementation of the project were conducted with the assigned Department of Defense Project Officer, the Chief of the Epidemiology Branch of NIAID and the NIAID Project Officer. After a scientific plan had been established both of the NIAID representatives left their positions. Transfer of information to new personnel was not optimal and, therefore, there was a period of adjustment as new personnel were coming on board and were briefed concerning the project. Once the new personnel at NIAID were in place, progress was greatly enhanced. With regard to the Department of Defense, shortly after the contract award, the contracts officer resigned her position and again a new officer was appointed.

In February 1989 new NIAID personnel, Army representatives and the study team met in Newark to review the original proposal and to plan implementation of the project. The result of this meeting was the development of a revised scope of work which was then submitted to the agencies involved. These revisions were submitted to the New Jersey Medical School Institutional Review Board (IRB) and to the Army Surgeon General's IRB. Patient accrual goals were set as defined above and study personnel worked on revisions of data collection forms, logistical details concerning the interaction between the Departments of

Pediatrics and Obstetrics/Gynecology, and laboratory procedures including those for maternal/neonatal drug screening and for handling and processing tissue (placenta, products of conception, etc.). Enrollment of patients was not possible until IRB approval was obtained. Delays in patient enrollment resulted in loss of some candidates for patient care positions. Laboratory personnel were successfully recruited.

While we awaited the Army IRB's review of the revised scope of work, study personnel were actively involved in the finalization of the data collection tools and other study materials as well as modification/expansion of our HIV research database to accommodate information from this project. A user friendly, menu-driven relational database application has been developed for research involving women and children with HIV infection over the past year. Members of the working group dealing with data developed study forms in conjunction with computer personnel and biostatistical consultants. Examples of the collection tools to be used in th project are found in APPENDIX A. It was anticipated that these would be validated in the field for a trial period as initial patients were enrolled. Subsequently, the computer application would be modified to include all of the form for this project. Data entry will be according to a "double-entry" system in order to assure that the information is of the highest quality.

On April 11, 1989 we received notification that the Army Surgeon General's IRB had received the latest revised proposal but that a significant amount of additional information was required before the committee would review it. These included a completely re-written revised proposal instead of the outline of changes that had been provided, some technical changes, documentation of New Jersey statues/laws regarding such issues as the use of products of conception in research. Request was made to limit enrollment of patients to 18 years of age or greater.

We were informed that the Army IRB would review the project at its May meeting. In the meantime, all of the same material that was provided to the Army IRB was submitted to the University IRB and approval of the revised proposal was granted on April 12, 1989 without qualification. However we were advised that no patients could be enrolled until the Army IRB approved the project.

All of the materials that were requested preliminary to the Army IRB review were submitted. Documentation was provided which clearly outlined that:

1) in New Jersey a pregnant woman, regardless of age was an emancipated minor and able to give informed consent. Sources from the state department of health and the law school at Seton Hall University were used for this information.
2) examination of products of conception are a routine part of obstetrical practice and represent a standard of care at the University Hospital in Newark. These tissues are currently being examined under these guidelines. Statements to this effect were provided from both the Chairman of the Department of Obstetrics and from the Acting Chairman of the Department of Pathology. The only thing that was being requested as part of this proposal was to examine this material for the presence of HIV, a procedure that would also be done as routine but no financial resources are currently available. Sources from the state department of Health and the Seton Hall Law School confirmed that there are no specific laws or statues in New Jersey regarding the use of this material in research other than the federal guidelines.

Following the Army IRB review we were informed that the proposal was denied. The basis for denial apparently was related to the use of products of conception and a question as to the military significance of the project. The latter issue was addressed swiftly and clearly. As a model of HIV infection, maternal-infant transmission has the potential to provide important clues as to the mechanisms of transmission and potential methods of preventing transmission that will benefit all. This model is key to certain projects already underway in the military, including Dr. Redfield's works regarding protective epitopes. Specimens from this project will greatly enhance the ability to study these important issues.

The proposal was yet again revised and the controversial areas were removed. Only patients who were >18 years were to be enrolled and we would not examine the products of conception. We felt that both of these compromises were made only because there was no other way to commence the project and that both could potentially significantly affect the validity of the data that will be derived from the project. Eliminating adolescents from the study population will affect enrollment, in that, currently one-third of the pregnant population at the University Hospital are <18 years of age. The failure to examine the products of conception will result in potential underestimation of the effects of HIV in pregnancy as well as the rates and mechanism of HIV transmission. A request was made to re-review the new proposal and the project was finally approved on June 14, 1989.

INFORMED CONSENT
MATERNAL FACTORS INFLUENCING PERINATAL TRANSMISSION OF HIV INFECTION

INTRODUCTION: HIV (AIDS virus) infection is an increasing problem in New Jersey. As many as one in twenty-two mothers delivering at this hospital may be infected with HIV (AIDS virus). Women that are infected with HIV (AIDS) may have as high as a 50% chance of passing the virus to their babies. AIDS is a serious illness associated with a high death rate. HIV (AIDS virus) is spread by blood (needle sharing, blood transfusion), sexual contact, breast-milk and through pregnancy (from mother to baby). You have been asked to participate in a study for women during pregnancy and up until 6 months after you deliver your baby. Being a part of this study means blood will be drawn to look for exposure to the AIDS virus (HIV antibody). A positive test means that you are infected with HIV (AIDS virus) and that your baby is at high risk for being infected. In addition to women who test positive some women who test negative for HIV infection will be asked to participate so that information about their pregnancy and the health of their baby can be compared to HIV positive women. Thus, women who are infected with HIV (AIDS virus) as well as women who are not infected with HIV (AIDS virus) are asked to be a part of this study. Women who have acquired HIV as a result of IV drug use and women who have acquired HIV by sexual contact with someone with HIV infection will be included.

STUDY: Being a part of this study means that at the same time that blood is drawn for exposure to the AIDS virus (HIV antibody), blood will also be drawn: a) to evaluate your immune system (ability to fight infection)and b) determine if you have been exposed to other viruses (germs) that commonly infect the newborn if present in the mother, in addition to routine blood drawn during pregnancy. During pregnancy there are known toxic substances that can effect your baby's development as well as your own health status. Thus, during pregnancy a sample of blood and urine will be obtained to monitor the presence of these toxic substances (i.e. alcohol, drugs). You will be examined at each visit during your pregnancy, immediately after delivery and at 6 weeks and 6 months after the baby is born. Periodic blood tests, urine tests and vaginal cultures will be done to monitor your health.

Additionally, an ultrasound (sound waves that produce a picture of the baby) will also be done at each visit to monitor the baby's development. If during the course of your routine OB/GYN care an amniocentesis is done, we will request a sample of left over amniontic fluid. However, an amniocentesis is not done as a part of this study. After delivery, the placenta (afterbirth) will be examined for evidence of HIV infection (AIDS virus).

Blood will be drawn from the baby at 6, 15 and 18 months to determine if he/she is infected with HIV (AIDS virus). If you are HIV infected, you will have the option of enrolling the baby in the CDC natural history of HIV infection study for long term follow up and care.

If during the course of this study any biopsy material is obtained as a part of regular medical care, a small portion will be examined for evidence of HIV infection (AIDS virus). Also, if your pregnancy results in a miscarriage or abortion of a non-viable fetus, we will examine the products of conception for HIV (AIDS virus). Advice regarding termination of pregnancy and the performance of medical abortions will not be a part of this study.

PROCEDURES/RISKS: Amount of blood taken each time will be safe, only one to two tablespoons from the baby and 4-5 tablespoons from you. Risks of blood drawing include possible pain and/or bruising at the site where the blood is drawn. There are no risks associated with an ultrasound (sound waves that produce a picture of the baby). Additionally, there is a risk of emotional upset of being diagnosed with a serious illness.

BENEFITS: Benefits of this study include comprehensive health care during pregnancy to monitor your health status and provide specalized follow-up. Additionally, the baby will be monitored for possible HIV infection and if necessary offered additional care at our pediatric AIDS clinic.

DISCLOSURE/ CONFIDENTIALITY: Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits or health care. Your may discontinue participation at any time upon notification to Dr. Connor or his associates without penalty or loss of benefits or health care to which your are otherwise entitled. Your rights to privacy will be strictly respected, with coded cards kept in a locked area. All results of this study are confidential. Only the investigators will have access to confidential data that identifies you and your child by name. It is the responsibility of the principal investigator to maintain strict confidentiality of all information. Only when a release is signed by the mother or legal guardian will any information gathered during this study be released. Every effort will be made to monitor confidentiality, but under court order, it is remotely possible that some information related to illegal conduct will have to be disclosed.

LIABILITY: Medical therapy at UMDNJ facilities will be offered to you for any physical injuries sustained as a consequence of your participation. Any such therapy not covered by a third party will be provided free of charge by UMDNJ. All claims should be made to the researcher or the Dean of the school who will arrange for a review by a committee to determine if the inquiry is the result of participation in the research. Federal regulations require that you be informed that in the event of injuries no additional financial compensation is available.

The principal investigator responsible for this study, his telephone number and address is: Edward M. Connor, M.D., Department of Pediatrics, MSB F-522, Newark, N.J. 201-456-5066 or 201-268-8484 (days) 201-272-1938 (evenings).

I hereby attest that I have read the entire consent form, or that it has been read to me, so that I understand it completely. I further attest that any and all questions of mine regarding this form or this study have been answered to my complete satisfaction.

Name: _____ Signature: _____

Witnessed: _____ Signature: _____

Date: _____

Signature of parent or legal guardian for infant.
I hereby attest that I am the _____ parent or _____ legal guardian (check one) of the subject _____ and that I agree to the above statement in its entirety.

Name: _____ Signature: _____

Witnessed: _____ Signature: _____

Date: _____

Signature of investigators or responsible individual and of witness.

I hereby attest that, to the best of my knowledge, the subject, (or his/her parent/legal guardian _____), has assimilated the entire content of the above consent form, and understands the study and its risks well, and that his/her questions and those of his/her parent or legal guardian have been accurately answered to his/her complete satisfaction, and those or his/her parent/legal guardian.

Name: _____ Signature: _____

Date: _____

Signature of reader/translator if the patient does not read English well.

The above signed parent or legal guardian, _____. does not read English well. I hereby attest that I both read English well and am fluent in _____. I further attest that I have translated for the parent or legal guardian and that he/she understands the content of the consent form and the study and that these questions have been answered to the complete satisfaction of the parent or legal guardian.

Name: _____ Signature: _____

Witnessed: _____ Signature: _____

Date: _____

CL:CONSENT

UMD
NEW JERSEY
University of Medicine & Dentistry of New Jersey
New Jersey Medical School

185 South Orange Avenue
Newark, New Jersey 07103-2757

PERMISSION TO RELEASE INFORMATION

I, _____ grant the Division of Allergy, Immunology and Infectious Disease of the Department of Pediatrics permission to release all appropriate reports and/or diagnostic information regarding HIV test results to UMDNJ- OB/GYN Department.

_____
Signature

_____
Date

_____
Witness

_____
Position

cl: releinfo

REGISTRATION INFORMATION

All of the following data except medical record number(s) and CDC study exit data must be entered into the computer upon study entry.

1. Registration #: _____

2. Study entry date: _____

3. Study exit date: _____
   Circle one of the following:
   a) death c) relocation
   b) withdrawal d) non-compliance

4. Division Code (may circle more than one)

a)	CDCO	e)	IMMU	i)	CSGU	m)	_____
b)	CHAP	f)	ALLE	j)	NIHO	n)	_____
c)	EBVO	g)	CONS	k)	DYSM	o)	_____
d)	IDCO	h)	NORM	l)	_____	p)	_____

5. Medical Record(s) #:
   a) University Hospital _____
   b) Children's Hospital of N.J. _____
   c) St. Josephs _____
   d) Jersey City Medical Center _____
   e) St. Michaels _____
   f) Other _____

6. Family Unit #: _____

7. Relationship Code (for patient): _____

8. Patient's name: _____/_____/_____
   (Last) (First) (M.I.)

9. Patient's DOB: _____

10. Patient's sex: _____

11. Is the patient known by any other name? yes ___ no ___
    If yes, name: _____/_____/_____
    (Last) (First) (M.I.)

12. Natural mother: _____/_____/_____
    (Last) (First) (M.I.)

13. Natural mother's DOB: _____

14. Natural father: _____/_____/_____
    (Last) (First) (M.I.)

15. Natural father's DOB: _____

_____
(Signature of Interviewer)

MOTHER'S

F L O W S H E E T

NAME: _____ **REGISTRATION #** _____

FORMS	INITIAL	24 to 28 wks	36 wks to term	DELIVERY	6 wks p.p.	6 mos. p.p.
1. Study consent	X					
2. Prenatal form	X					
3. Registration	X					
4. Risk assessment	X					
5. Hx & P.E.	X	P.E. only	P.E. only	P.E. only	x	X
6. Social history	X					
7. Genogram	X			X		
8. Delivery visit				X		
LAB WORK						
1. CBC with diff.	X		X	X	X	X
2. Sickle Cell Electro.	X					
3. VDRL	X			X		
4. SMAC	X			X		
5. Hepatitis Profile	X					
6. Rubella Ab	X					
7. Toxo titer	X		X			
8. EBV titer		X		X		
9. Type & screen	X					
10. Serum ethol. screen	X	X	X	X	X	X
11. Ig G/A/M	X			X		
12. HIV Ab/Ag	X	X	X	X	X	X
13. HTLV-1 Ab	X	X	X	X	X	X
14. Neutralizing Ab	X	X	X	X	X	X

NAME A_____ REGISTRATION # _____

FORMS	INITIAL	24 to 28 wks	36 wks to term	DELIVERY	6 wks p.p.	6 mos p.p.
15. T & B cell	X	X	X	X	X	X
16. Mitogen & Antigen	X	X	X	X		
17. HIV culture	X	X	X	X	X	X
18. Serum & cell save	X	X	X	X	X	X
19. Urinalysis	X	X	X	X	X	X
20. Urine CMV	X			X		
21. Urine toxicology	X	X	X	X	X	X
22. Urine save	X	X	X	X	X	X
23. Cervical chlamydia, Herpes, & GC culture	X					
24. Placenta				X		
25. Ultrasound	X	X	X			

BABY'S
FLOW SHEET

Name:_____ D.O.B:___/___/___ Registration #_____

Lab Work	Amt. in cc Whole blood	6 mo.	15 mo.	18 mo.
Ig G/A/M	3 cc			
HIV Elisa WB	3 cc			
Serum Save	3.5 cc			
[illegible]ll Save	3.5 cc			
ial History				
History & P. exam.				

NAME: ______________________ REG. # ______________________

D.O.B. ___/___/___ G.A.: ______________________

DATE AGE	HIV AB	HTLV-1	SERUM P24	CSF P24	CELL CULT	ATHC	IG G/A/M/	H/H

PHYSICAL EXAM

____ Initial Visit
____ Emergency
____ 24 to 28 wk.
____ 36 wk. to term
____ Postpartum immediately
____ 6 wks. postpartum
____ 6 mons. postpartum

Name: _____ *Date: ____/____/____

*Registration #: _____ D.O.B.: ____/____/____

M.R. #: _____ Last Menstrual Period: ____/____/____

Wks. Gestation: _____ EDC: ____/____/____
(By dates clinically sonogram CIRCLE ONE)

*1. Weight in kgs	*1. _ _ _._ _
*2. Urine analysis	*2.
*a) protein	*a) ____
*b) glucose	*b) ____
*c) ketones	*c) ____
*3. BP	*3. _ _ _/_ _
*4. Fundal Height in cms.	*4. _ _ _
*5. FHR	*5. _ _ _

---

6. EXAM

	Norm.	Abnorm.
A. SKIN		
B. LYMPH		
Cx.		
Inguinal		
Ax.		
C. HEENT		
Thrush		
Parotid Swelling		
D. LUNGS		
Cough		
Wheezing		
Rales		

EXAM

	Norm.	Abnorm.
D. LUNGS (cont)		
Rhonchi		
Cyanosis		
Clubbing		
E. HEART		
F. ABDOMEN		
Distention		
Splenomegaly		
Heptomegaly		
(Record #cm below costal border)		
G. Genitalia & Anus		
H. Musculoskeletal		
I. Neuro.		
DTR		

*7. PPD P=positive N=negative *7. ____

a) Results _____

b) CXR _____

*8. Medical Diagnosis *8.

*a) _____ *a) _ _ _._ _ _

*b) _____ *b) _ _ _._ _ _

*c) _____ *c) _ _ _._ _ _

*d) _____ *d) _ _ _._ _ _

*e) _____ *e) _ _ _._ _ _

*f) _____ *f) _ _ _._ _ _

*g) _____ *g) _ _ _._ _ _

*8. Medical Diagnosis

*h) _____

*i) _____

*j) _____

*k) _____

*l) _____

*m) _____

*n) _____

*o) _____

*p) _____

*q) _____

*r) _____

*s) _____

*t) _____

*8.

*h) _ _ _.- _ _

*i) _ _ _.- _ _

*j) _ _ _.- _ _

*k) _ _ _.- _ _

*l) _ _ _.- _ _

*m) _ _ _.- _ _

*n) _ _ _.- _ _

*o) _ _ _.- _ _

*p) _ _ _.- _ _

*q) _ _ _.- _ _

*r) _ _ _.- _ _

*s) _ _ _.- _ _

*t) _ _ _.- _ _

*9. Nursing Diagnosis

*a) _____

*b) _____

*c) _____

*d) _____

*e) _____

*f) _____

*g) _____

*h) _____

*i) _____

*j) _____

*k) _____

*l) _____

*m) _____

*n) _____

*9.

*a) _ _ _ .- _ _

*b) _ _ _.- _ _

*c) _ _ _.- _ _

*d) _ _ _.- _ _

*e) _ _ _.- _ _

*f) _ _ _.- _ _

*g) _ _ _.- _ _

*h) _ _ _.- _ _

*i) _ _ _.- _ _

*j) _ _ _.- _ _

*k) _ _ _.- _ _

*l) _ _ _.- _ _

*m) _ _ _.- _ _

*n) _ _ _.- _ _

*9. Nursing Diagnosis

*9.

*o) _____ *o) ___.___

*p) _____ *p) ___.___

*q) _____ *q) ___.___

*r) _____ *r) ___.___

*s) _____ *s) ___.___

*t) _____ *t) ___.___

*10. CDC Classification *10. ____

11. PLAN _____

_____

_____

_____

_____

12. LABORATORIES

Initial Visit

CBC w/diff.	____	Serum Alcohol Level	____
VDRL	____	Serum Drug Screen	____
Rubella titer	____	Ig G/A/M	____
Hepatitis Screen	____	HIV Ab/Ag	____
Type & Screen	____	HTLV-1 Ab	____
Sickle Cell	____	T & B cells	____
Toxo. titer	____	Mitogens & Antigens	____
SMA 18	____	HIV culture	____
Urine toxicology	____	Serum & Cell save	____
Urine CMV	____	Chlamydia Culture (cx)	____
Urinalysis	____	Herpes Culture (cx)	____
Urine save	____	GC Culture (cx)	____
Neutro. Ab	____	Other _____	
		_____	

24 to 28 wks.

EBV titer	____	HTLV-1 Ab	____
Serum Alcohol	____	T & B cells	____
Serum Drug Screen	____	Mitogens & Antigens	____
Urine toxicology	____	HIV Culture	____
Urine save	____	HIV Ab/Ag	____
Urinalysis	____	Neutro. Ab	____
Serum & Cell save	____	Other _____	
		_____	

12. LABORATORIES

36 wks to term

CBC W/diff.	____	HIV Ab/Ag	____
Toxo titers	____	HTLV-1 Ab	____
Serum Alcohol level	____	T & B Cells	____
Serum Drug Screen	____	Mitogens & Antigens	____
Urine toxicology	____	HIV Culture	____
Serum & Cell save	____	Neutrolyzing Ab	____
Urine save	____	Rubella titer	____
Urinalysis	____	Other ____	
Sickle Cell	____	____	

DELIVERY

CBC w/diff	____	HIV Ab/Ag	____
VDRL	____	HTLV-1 Ab	____
SMA 18	____	T & B Cells	____
EBV titers	____	Mitogens & Antigens	____
Serum Alcohol level	____	Neutrolyzing Ab	____
Serum Drug level	____	HIV culture	____
Ig G/A/M	____	Serum & Cell save	____
Urine toxicology	____	Urine save	____
Urine CMV	____	Placenta	____
Urinalysis	____	Other ____	
		____	

6 Wks. Postpartum

CBC w/diff	____	HIV Ab/Ag	____
Serum Alcohol level	____	HTLV-1 Ab	____
Serum Drug level	____	T & B Cells	____
Urine toxicology	____	Neutrolyzing Ab	____
Urine save	____	HIV culture	____
Serum & Cell save	____	Other ____	
		____	

6 months postpartum

CBC w/diff	____	HIV Ab/Ag	____
Serum alcohol level	____	HTLV-1 Ab	____
Serum drug level	____	T & B cells	____
Urine toxicology	____	Neutrolyzing Ab	____
Urine Save	____	HIV culture	____
Serum & Cell Save	____	Urine CMV	____
Other ____			
____			

13. ANTEPARTUM TESTING (1=yes 2=no) 13. ____
(If yes, complete anteparum testing sheet)

____
(SIGNATURE)

PRENATAL VISIT

_____Initial Visit
_____Emergency
_____24-28
_____36-term
_____Postpartum_____Immediate
_____6 weeks
_____6 months

Name:_____ *Date:___/___/___

*Registration #:_____ D.O.B:___/___/___

M.R.#_____ Last Menstrual Period:___/___/___

Wks Gestation:_____ EDC:___/___/___
(Circle: Clinical dates or sonogram)

HEALTH CARE VISIT

*1. Have you been to any other doctor, E.R. or hospitalized since your last visit here? (Record # of times 00-99) *1.__ __
Explain:_____
_____

*2. Have you been to any doctor about being pregnant prior to this visit? (Record # of times) *2.__ __

GYNECOLOGICAL HISTORY

Menarchie date: ___/___/___

Interval menses____days Length of menses____days

1 = yes 2 = no 3 = not applicable

3. Hx of menorrhalgia 3._____

4. Hx of aminorrhea 4._____

5. Hx of dysemnorrhea 5._____

6. Hx of infertility 6._____

7. Incompetent Cx 7._____

8. Uterine Abnormality 8._____
specify_____

9. Abnormal PAP smear 9.____
Specify_____

Colposcopy referral ____yes ____no
Results_____

10. Hx of salpingitis 10.____

11. Hx of endometritis 11.____

12. Hx of sexual abuse 12.
a) Rape a. ____
b) Incest b. ____
c) unknown c. ____

13. Are you using contraception? 13.____
Type_____

14. Last GYN Exam___/___/___ 14.____

OBSTETRICAL HISTORY

1 = yes 2 = no 3 = not applicable
(items 8-13 and 16-19)

15. Substance abuse (Ethol, Drugs, Cigarettes) 15.____
If yes, specify _____

16. P I H 16.____
PET_____
Chronic hypertension_____
Eclampsia_____

17. IUGR 17.____

18. Preterm Labor 18.____

19. 3rd Trimester Bleeding 19.____
a) Placenta Previa_____
b) Abruptio Placenta_____

20. Multiple Birth 20.____

21. Gestational Diabetes 21.____
a) Insulin a) ____
b) Diet b) ____

22. C-Section 22.____
a) Repeat a) ____
b) VBAC b) ____

*23. Rh incompatibility *23._____
Explain_____

*24. Gravida (00 to 25) *24.__ __

*25. Para (00 to 25) *25.
*a) pre-term *a) __ __
*b) full term *b) __ __
*c) abortion *c) __ __
*d) miscarriage *d) __ __
*e) # of live births *e) __ __
*f) Ectopic (R)_____) *f) __ __
(L)_____)

Describe any abortions/miscarriages_____
_____

Record multiple births_____

26. Are all of your children living? 26._____
If no, specify sex, age of death and
cause of death_____

27. Were any of your children born with a birth defect? 27._____
If yes, specify_____

28. Have any of your children been tested for HIV. 28._____
If yes, specify sex, age and result_____
_____

PAST HEALTH HISTORY

1 = yes 2 = no 3 = not applicable

29. Heart Disease_____ 29._____

30. Lung Disease_____ 30._____

31. Renal Disease_____ 31._____

32. Diabetes_____ 32._____

33. Lupus erythematosus_____ 33._____

34. Multiple Sclerosis_____ 34._____

35. Seizure Disorder_____ 35._____

36. Cancer_____ 36._____

37. Hypertension_____ 37.____

*38. Infections *38.

*a. cystitis *a. ____
*b. pyelonephritis *b. ____
*c. herpes *c. ____
*d. vaginal candidiasis *d. ____
*e. gonorrhea *e. ____
*f. syphilis *f. ____
*g. chlamydia *g. ____
*h. venereal warts *h. ____
*i. P.I.D. *i. ____
*j. tuberculosis *j. ____
*k. PCP *k. ____
*l. pneumonia *l. ____
*m. meningitis *m. ____
*n. hepatitis B *n. ____
*o. mononucleosis (EBV) *o. ____
*p. CMV *p. ____
*q. measles *q. ____
*r. german measles *r. ____
*s. chicken pox *s. ____
*t. mumps *t. ____
*u. shingles *u. ____
*v. thrush *v. ____
*w. other_____
_____

39. Other problems_____ 39.____
_____

40. Have you ever had an operation? 40.____
If yes, specify date and type_____
_____

41. Review of Systems 41.____

General:_____
_____
Skin/Lymph:_____
_____
HEENT:_____
_____
Cardiorespiratory:_____
_____
GI:_____
_____
OB/GYN:_____
_____
Musculoskeletal:_____

*42. Therapies *42.

1 = yes 2 = no 3 = not applicable

*a. Blood or Blood product transfusion *a. _____

*b. O2 Via_____ *b. _____
*c. Respirator_____ *c. _____
*d. Respirator Tx_____ *d. _____
*e. Medications *e. _____
*1. analgesics *1. _____
*2. vitamins *2. _____
*3. Fe *3. _____
*4. anticonvulsants *4. _____
*5. bronchiodilators *5. _____
*6. insulin *6. _____
*7. antidiabetic *7. _____
*8. methadone *8. _____
*9. diuretics *9. _____
*10. cardiac preps (other than diuretics) *10._____
*11. hyperalimentation *11._____
*12. lipids *12._____
*13. antibiotic *13._____
*14. antiviral *14._____
*15. antifungal *15._____
*16. antiparasitic *16._____
*17. rhogam *17._____
*18. other_____ *18._____
*19. other_____ *19._____

*43. Procedures *43.

*a._____ *a._ _ _
*b._____ *b._ _ _
*c._____ *c._ _ _
*d._____ *d._ _ _
*e._____ *e._ _ _

_____
Interviewer

CNS

*65. Seizure Disorder *65. ___

*66. Hypoxic Brain Syndrome *66. ___

*67. IVH (grade _____) *67. ___

*68. Cardiovascular *68. ___
Specify: _____

*69. G.U. *69. ___
Specify: _____

*70. Endocrine *70. ___
___ IDM
___ Thyroid
___ Adrenal
___ Other _____

*71. Neoplastic *71. ___

*72. Referral Source *72. ___
1 = Referred by Nursery/Ped
2 = Referred by OB/GYN
3 = Screen
4 = Previously known by CHAP
5 = Known to CDC
6 = Others _____.

_____
(Signature)

Delivery Visit

Name: _____ *Date: _____

*Registration #: _____ MR #: _____

Sex: _____ DOB: _____

Neonatal Data:

*1. Born — *1. ____
1 = enroute
2 = home
3 = University Hospital

*2. Blood type — *2. ____
1 = group A
2 = group B
3 = group AB
4 = group O

*3. Rh — *3. ____
P = positive
N = negative

*4. Coombs — *4. ____
P = positive
N = negative

*5. PKU — *5. ____
P = positive
N = negative

*6. Galactosemia — *6. ____
P = positive
N = negative

*7. TSH _____ mg/dl — *7. _._

*8. T4 _____ mg/dl — *8. _._

*9. How many infants were born during this pregnancy? (0.0 to 9.0) — *9. _.0

*10. How many infants were born alive? (0.0 to 9.0) — *10. _.0
(If response to question 9 and 10 differ, explain)

_____

_____

*11. Gravida (00 to 99) *11. _ _

*12. Para (00 to 99) *12.
*a) pre-term *a. _ _

*b) full term *b. _ _

*c) abortion *c. _ _

*d) miscarriage *d) _ _

*e) # of live births *e) _ _

*13. Gestational Age *13. ___
1 = AGA

2 = SGA

3 = LGA

*14. Gestational Age (best judgement in weeks, 00 to 99) *14. _ _
Also, record gestational age below:
a. date _____ wks.

b. Dubowitz _____ wks.

c. ultrasound_____ wks.

GROWTH PARAMETERS

*15. Birth weight in grams (0000 to 9999) *15. _ _ _ _

*16. Birth weight percentile (00 to 99) *16. _ _ %
04 = < 5% 99 = > 95%

*17. Birth length in cms. (00.00 to 99.99) *17. _ _._ _

*18. Birth length percentile (00 to 99) *18. _ _ %
04 = < 5% 99 = > 95%

*19. Birth HC in cms. (00.00 to 99.99) *19. _ _._ _

*20. Birth HC percentile (00 to 99) *20. _ _ %
04 = < 5% 99 = > 95%

INTRAPARTUM COMPLICATIONS

1 = yes 2 = no

*21. Fetal distress *21. ___
a) Cord pH (arterial/venous)

*22. Chorioamnionitis *22. ___
a) Clinical
b) Subclinical

*23. Failure to Progress *23. ___

*24. Preterm Labor *24. ___
Tocolytics Yes____ No____

Successful_____ Failure_____

*25. PROM (>24 hrs) record number of hrs. _____ *25. ___

*26. Meconium stain *26. ___

*27. Abruptio placenta *27. ___

*28. Malpresentation *28. ___

*29. Prolonged 2nd stage *29. ___

*30. Hypotonic uterus *30. ___

*31. Prolapse cord *31. ___

*32. Maternal hemorrhage *32. ___

*33. Other_____ *33. ___

DELIVERY

*34. Type of Delivery (may choose only one) *34. ___
1 = Vertex Vaginal
2 = C-Section indication_____
3 = Breech Vaginal_____
4 = Forceps indication_____
5 = Vacuum indication_____

*35. Anesthesia *35. ___
a) Local_____ Pudendal_____
c) Epidural_____ General_____

*36. Umbilical Cord Acid-Base Imbalance *36. ___
a) arterial ph _._
b) venous ph _._

APGAR (record score, 00 to 10)

*37. a) 1 minutes *a)__ __
b) 5 minutes *b)__ __
c)10 minutes *c)__ __

*38. Was resuscitation required? *38.____
Specify:
*a) bag and mask *a) ____
*b) incubation *b) ____
*c) medication *c) ____
*d) 02 *d) ____
*e. other *e) ____

Postrapartum Complications

*39. Anemia *39.____
*40. Hypertension *40.____
*41. UTI *41.____
*42. Endometritis *42.____
*43. STD *43.____
*44. withdrawal *44.____
*45. others *45.____

NEONATAL COMPLICATIONS

1 = yes 2 = no

Respiratory Problems

*46. Transient tachypnea *46.____

*47. Meconium Aspiration *47.____

*48. Hyaline Membrane Disease *48.____

Respiratory Problems

*49. Apnea of Prematurity *49.____

*50. Air leak (site: _____) R ___ L ___ *50.____

*51. Pneumonia (type _____) *51.____

*52. Respiratory difficulty of unknown etiology *52.____

Birth Asphyxia

*53. Acidosis (record lowest pH, 0.0 to 9.9) *53. _._
0.0 = acidosis not present

*54. Hypotension *54. ___

*55. Neurologic Depression *55. ___

Hematologic

*56. Polycythemia *56. ___

*57. Coagulation *57. ___

*58. Hyperbilirubinemia *58. ___
___ physiologic (< 12 mg%)
___ etiology undetermined
___ RH
___ ABO

*59. Birth trauma *59. ___
Specify type: Fx _____ Soft tissue _____
Nerve _____ Internal organ _____

*60. Congenital Anomalies (Specify type) *60. ___

Infection _____

Skin and Skin appendages _____

Craniofacial _____

Eyes and Ears _____

Respiratory _____

Cardiac _____

G.I. _____

G.U. _____

Musculoskeletal _____

Syndromes _____

Other _____

Metabolic

*61. hypoglycemia *61. ___

*62. hypocalcemia *62. ___

*63. hypoproteinemia *63. ___

*64. drug withdrawal (specify: _____) *64. ___

NEW JERSEY

UNIVERSITY HOSPITAL
150 Bergen Street
Newark, New Jersey 07103-2425
(201) 456-4300

RISK BEHAVIOR ASSESSMENT

NAME		DATE *
M.R. #	REGISTRATION # *	DATE OF BIRTH

* 1. WHERE WERE YOU BORN ? *1.____

1= USA 2= AFRICA 3= HAITI 4= CUBA 5= PUERTO RICO 6= OTHER _____

* 2. TO WHAT POPULATION GROUP DO YOU BELONG ? *2.____

1= WHITE, NON-HISPANIC 3= HISPANIC 5= AMERICAN INDIAN OR ALASKAN NATIVE 6= OTHER

2= BLACK, NON-HISPANIC 4= ASIAN OR PACIFIC ISLANDER _____

3. HAVE YOU EVER HAD A BLOOD TRANSFUSION, PLATELETS, FRESH FROZEN PLASMA, WBC'S AND / OR CRYOPRECIPITATE: *3.____

RECORD YEAR _____ TYPE OF TRANSFUSION _____ 1= YES 2= NO 8= UNKNOWN 9= NO COMMENT

PROMPT CLIENT WITH FOLLOWING SUGGESTIONS:

A. SURGERY, INCLUDING A ONE DAY SURGICAL PROCEDURE
B. SPONTANEOUS, ELECTIVE OR THERAPEUTIC ABORTION
C. ORGAN TRANSPLANT OR GRAFT
D. BLEEDING DISORDER
E. OTHER _____

* 4. HAVE YOU EVER BEEN ARTIFICIALLY INSEMINATED ? *4.____

1= YES 2= NO RECORD YEAR _____

* 5. HAVE YOU EVER USED ANY STREET DRUGS (NON IV) THAT YOU INHALE, SNORT OR SWALLOW ? *5.____

1= YES 2= NO 9= NO COMMENT

*6. ARE YOU CURRENTLY (NOW) USING THESE DRUGS ? *6.____

1= YES 2= NO 9= NO COMMENT

IF YES: A. NAME OF DRUG _____

B. (✓): _____ INHALE _____ SNORT _____ SWALLOW

C. HITS / DAY _____

*7. HAVE YOU EVER USED DRUGS THAT YOU MUST PUT IN YOUR VEIN OR UNDER YOUR SKIN WITH A NEEDLE ? *7.____

1= YES 2= NO 9= NO COMMENT

*8. ARE YOU CURRENTLY (NOW) USING THESE DRUGS ? *8.____

1= YES 2= NO 9= NO COMMENT

IF YES: A. NAME OF DRUG _____

B. (✓) _____ IV _____ SKIN POPPING

C. HITS / DAY _____

9. HAVE YOU EVER SHARED NEEDLES ? *9.____

1= YES 2= NO 9= NO COMMENT

*10. DO YOU CURRENTLY (NOW) SMOKE CIGARETTES ? *10.____

1= YES 2= NO 9= NO COMMENT

IF YES: CIGARETTES / DAY _____

GENOGRAM

□ - Male
○ - Female
△ - Pregnancy
▲ - Abortion

——— - Marriage
- - - - - Co-habitation/Union by offspring
—//— - Divorce
■ ● - Deceased

) - Offspring

NOTE: Abortions will not be given relationship codes unless the products of conception are available for data collection.

ANTEPARTUM TESTING

_____Initial Visit
_____Emergency
_____24-28
_____36-term
_____Postpartum_____Immediate
_____6 weeks
_____6 months

Name:_____*Date:___/___/___

*Registration #:_____MR#:_____

Sex:_____DOB:_____

*1. Doppler flow studies Umbilical *1._____

*a. S/D *a.__.__

*b. PI *b.__.__ __

*c. Resistance Index *c.__.__ __

*2. Uterine Artery *2.

*a. S/D *a.

*1. Right *1.__.__
*2 Left *2.__.__

*b. PI *b.

*1. Right *1.__.__
*2. Left *2.__.__

*c. Resistance Index *c.__.__ __

*3. Ob/sonogram *3.

*a. FHR *a._____

1 = Yes 2 = No

*b. Amniotic fluid *b._____

N = normal A = abnormal

*c. GA by dates — *c.___ ___
*d. GA by sonogram — *d.___ ___
*e. BPD — *e.___ ___
*f. AC — *f.___ ___
*g. HL — *g.___ ___
*h. EFW — *h.___ ___

*1. BPD/AC — *1.__ __ __ __
*2. FL/AC — *2.__ __

*i. Placenta — *i._____

COMMENTS_____

_____

*4. Antepartum Testing — *4.
*a. NST — *a._____

R = Reactive N = Non-reactive

*b. CST — *b._____

P = Positive N = Negative S = Suspicious U = Unsatisfactory

*c. Niple Stimulation — *c._____

P = Positive N = Negative S = Suspicious U = Unsatisfactory

*d. Biophysical profile — *d.
*1. Amniotic fluid — *1._____
*2. Fetal movements — *2._____
*3. Tone — *3._____
*4. Fetal breathing — *4._____

_____
(Signature)

MOTHER'S PSYCHOSOCIAL HISTORY

Registration #: _____ *Date: _____

Gestational Age (weeks): _____ D.O.B.: _____

Type of Visit: ___ initial
___ 24 - 28 wks
___ 36 - term
___ delivery
___ 6 wks. p.p.
___ 6 mos. p.p

Patient's History

*1. Ethnic Origin *1.____
1 = Caucasion 4 = Hispanic
2 = Afro-American/Black 5 = Afro-American and Caucasion
3 = Haitian Origin 6 = Other _____

*2. Marital Status *2.____
1 = Never Married 5 = Widow
2 = Married 6 = Common-Law Marriage
3 = Separated 7 = Other _____
4 = Divorced

*3. How many children (natural born) do you have? *3._ _
Explain:_____
_____

*4. Level of Education (Record last yr. completed.) *4._ _

*5. Living Situation *5.___
1 = Lives alone 4 = Lives w/children & s.o.
2 = Lives alone w/children (explain_____)
3 = Lives w/friend or lover 5 = Other_____

Comments_____

*6. Are you currently employed? *6.___
1 = No 4 = Part-time/Permanent
2 = Full-time/Permanent 5 = Part-time/Temporary
3 = Full-time/Temporary 6 = Other (_____)

*7. Financial Resource(s) *7. ____

1 = Employment/Wages 5 = SSD/SSI
2 = AFDC 6 = Municipal welfare
3 = Child support 7 = Medicaid
4 = Food stamps 8 = Other (explain _____)
9 = None

Comment_____

*8. Total Income (per month) *8._ _ _ _ _ _.00

*9. Are you enrolled in a social service agency? *9. _____

1 = None 4 = CMHC
2 = WIC 5 = Other (_____)
3 = DYFS

*10. How many sexual partners have you had in the past 10 years?(with or without a condom) *10. _ _

*11. Length of relationship with the father of the baby ? *11. _

1 = < month 4 = 6 - 12 months (pre-conception)
2 = 1 - 3 months 5 = 13 - 24 months
3 = 3 1/2 - 5 1/2 months 6 = other (_____)

*12. Is your current relationship supposedly monogamous? *12._

1 = Yes 2 = No
3 = No Comment

*13. Did you ever suspect that your sexual partner has had sex with someone else? *13. _

1 = Yes 2 = No
3 = No comment

*14. Have you ever had sex with someone else other than the father of the baby since your last/current pregancy? *14. _

1 = Yes 2 = No
3 = No comment

*15. Were you ever diagnosed with any sexual transmitted disease during your current relationship? *15. _

1 = Yes 2 = No
3 = No comment

*16. Does your sexual partner(s) know your diagnosis? *16 _____

1 = Yes 2 = No 9 = no comment
Explain _____

*17. Has your partner (sexual or needle sharing) been tested for HIV? *17. _____

1 = Yes 2 = No 8 = unknown 9 = no comment
Explain _____

*18. Have you ever served time in prison? *18. _____

1 = Yes 2 = No 9 = no comment
Explain _____

*19. Has your sexual partner(s) ever been incarcerated? *19. _____
1 = Yes 2 = No 8 = unknown 9 = no comment
Explain _____

*20. Have you ever been treated for a psychological disorder? *20. _____
1 = Yes 2 = No 9 = no comment
Diagnosis/Reason:
Year:
Place:

*21. Kubler-Ross' Phases of anticipatory grief: *21. _____
1 = Denial/Shock 4 = Depression/Beginning Acceptance
2 = Anger/Irritability 5 = True Acceptance
3 = Bargaining 6 = Not Applicable

Explain:_____
_____

*22. Defense mechanism (if any) *22. _____
1 = Denial 5 = Regression
2 = Displacement 6 = Depersonalization
3 = Rationalization 7 = Projection
4 = Repression 8 = Other (Explain_____)
9 = Not Applicable

Strengths:
_____
_____
_____

Weakness:
_____
_____
_____

Social Work Impression
_____
_____
_____
_____
_____

Plan:
_____
_____

_____
Staff Signature/Title